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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,793	10/01/2001	Benedito Da Silva	TIN-0017	5160
23413	7590	06/03/2004	EXAMINER COOK, REBECCA	
CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/868,793	Applicant(s) DA SILVA, BENEDITO	
	Examiner Rebecca Cook	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12, 17, 20-22, 24 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12, 17, 20-22, 24, 27-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/5/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The amendment filed November 5, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The text submitted to replace the 2nd and the 3rd full paragraphs on page 2 of the Substitute Specification does not correspond to the text in the Substitute Specification received September 30, 2003. No support is seen in the original specification for the recitation in paragraph 2 "The ideal dilution is 1 vol% of the active compound based on the volume of the vehicle." Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant's amendment to the specification overcomes the earlier objection under 35 USC 132.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Claims 28-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

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While the specification recites "upper respiratory disorder," it discloses that the intent of the instant invention is to treat sinusitis and rhinitis. It is not seen that there is any intent to treat other "upper respiratory disorder[s]" which would include polyps, Wegener's granulomatosis, anosmia, neoplasm, epistaxis or deviated or perforated septum.

Claims 28 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 28 the phrase "a mixtures" is grammatically incorrect. It appears that the intent is to recite "a mixture."

In claim 31 the phrase "a balanced mixtures" is grammatically incorrect. Furthermore, the word "balanced" has been deleted from claim 12. Amending the phrase to recite "a mixture" will overcome this rejection. It is noted that claim 12 has been amended in this way.

In view of the amendments to the claims the earlier rejections under 35 USC 112, paragraph two are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12, 17, 20-24, 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 27 21 014 (Reith) in view of Remington's Pharmaceutical Sciences (Remington).

Reith discloses (abstract) that α -hydroxy propionic acid can be used to treat allergies and viral diseases. The claims differ over Reith in reciting a specific concentration of α -hydroxy propionic acid and nasal administration. However, once a method of using a compound is known, in the absence of unexpected results, it is within the skill of the artisan to determine the optimum route of administration and concentration of the active ingredient.

Dependent claim 12 and claims 28-32 differ over Reith in reciting a specific vehicle. However, Remington discloses that it is well-known to use glycerin as a vehicle for preparations for nasal administration. It would therefore be obvious to one of ordinary skill in the art to use the instant glycerin as a vehicle for the α -hydroxy propionic acid.

Applicant argues that there is no suggestion by Reith to treat sinusitis and rhinitis associated with bacteria and/or yeast. This is not persuasive. Applicant does not limit the instant method to treating only these conditions. As recited the instant method includes sinusitis caused by allergies and viruses.

Applicant further argues that Reith does not teach that α -hydroxy propionic acid is suitable for or upper respiratory disorders. This is not persuasive, since said disorders include the allergy and viruses taught by Reith.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 272-0584.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 703-872-9806

Rebecca Cook

A handwritten signature in black ink, appearing to read 'Rebecca Cook', written in a cursive style.

Primary Examiner
Art Unit 1614

May 31, 2004